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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,145	06/19/2003	Sang-Yup Lee	HYLEE80.001C1	5042
20995	7590	10/06/2006	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			MINNIFIELD, NITA M	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/600,145	LEE ET AL.
	<b>Examiner</b> N. M. Minnifield	<b>Art Unit</b> 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 17 July 2006.
- 2a) This action is **FINAL**.                                   2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 27-31 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-26 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 09 June 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All   b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### *Response to Amendment*

1. Applicants' amendment filed July 17, 2006 is acknowledged and has been entered. Claims 1,4-17 and 19-24 have been amended. New claims 25-31 have been added. Claims 1-31 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or comments, with the exception of those discussed below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Newly submitted claims 27-31 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the fusion protein is independent and distinct from the expression vector that has been examined on the merits. For example, the fusion protein is classified in class 530, subclass 350 and the expression vector is classified in 435/320.1. These two groups are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). The different products (polypeptides/fusion protein and expression vector) are distinct from one another because they are structurally, physically, and functionally distinct chemical entities that lack a common function and core structure.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original

presentation for prosecution on the merits. Accordingly, claims 27-31 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Claims 1-26 is being examined in this application.

5. Receipt is acknowledged of papers (2001-0048881 Republic of Korea application and PCT/KR02/01547) submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

6. Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-26 are vague and indefinite in the recitation of “fragment” (see line 3). Does this fragment refer to the fragment of the OmpF gene as set forth in line 1 of claim 1 or is this a fragment of the gene of interest?

This rejection is maintained for the reasons of record. Applicant's arguments filed July 17, 2006 have been fully considered but they are not persuasive. Applicants have asserted that claim 1 has been amended to recite an OmpF gene encoding all or a fragment of an OmpF protein. However, it is still not clear what is encompassed by the recitation “fragment of the OmpF protein” (see line 3 of claim 1). How much of the OmpF protein is required to constitute a fragment of the OmpF protein?

7. The Office acknowledges the deposit information as required by the Budapest Treaty for accession number KCTC 1026BP filed July 17, 2006; these papers are now a part of this application file.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 7, 11, 12 and 15-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is vague and indefinite in the recitation of “protein of interest comprises β-endorphin”. Is the protein something else other than the β-endorphin? It is not clear what Applicants intend.

Claims 15-26 are vague and indefinite in the reactions of “separating at least part of the fusion protein from the medium”. It is not clear what Applicants intend. Does this mean that a portion (some amount less than the total amount of fusion protein secreted) of the total fusion protein that is secreted into the medium is actually separated from the medium? Or does Applicant intend that only a fragment (for example only a fragment of the β-endorphin) of the fusion protein that is secreted into the medium be separated?

Claim 22 is vague and indefinite; it is not clear when this new method step, “further comprising removing the microorganism from the media”, occurs in relation to the method steps already recited in claim 15.

Claims 25 and 26 are vague and indefinite; it is not clear when the cleaving step, “further comprising cleaving the fusion protein at the cleavage site...” occurs in relation to the methods steps already recited in claim 15.

Claims 20 and 21 recite the limitation “enzyme” in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 24 recites the limitation “collecting” in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 is vague and indefinite in the recitation of “protein of interest comprises β-endorphin”. It is not clear what Applicants intend. Is the protein of interest β-endorphin or β-endorphin and some other unknown protein?

Claims 11, 12 and 17-19 are vague and indefinite in the recitation of “microorganism comprises...”. It is not clear what the microorganism is; what does Applicant intend.

9. No claims are allowed.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is

filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Albert M. Navarro can be reached on 571-272-0861. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



N. M. Minnifield

Primary Examiner

Art Unit 1645

NMM

October 2, 2006